Approved for use through 10/31/2002. OMB 0851-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	Substitute for form 1449A/PTO					Complete if Known		
11	NEO		TION DISCLO	CLIDE	Appl	ication N .	10/660,434	
					Filing	g Date	September 10, 2003	
STATEMENT BY APPLICANT		First	Named Inventor	Guennadi V. Glinski				
					Art Ú	nit	Not yet known	
	n	nailed	12/4/03	ō E \	Exam	niner Name	Not yet known	
Shee	Sheet 1 of 2		Attori	ney Docket Number	23543-07570			
		<del></del>		ब्री	<del></del>			
			L DEC 1	5 2003 ju				
			E .	<i>₩</i> .s.	PATE	NT DOCUMENTS		
			Document No.	ass				
	niner	Cite No.1	Number - Kind Code	Date MM-DD-YY	~~		Name of Patentee or	
Initia	ais	NO.	known) US-	MIM-DU-TT	* *		Applicant of Cited Document	
L		<u></u>	1 03-			l		
				FORFI	CN DV.	TENT DOCUMENTS		<del></del>
		1	Foreign Patent Docum	· · · · · · · · · · · · · · · · · · ·	OILLY	TERT BOODINERTS		Τ
Fxar	miner	Cite	Country Code <sup>3</sup> –	Publication	Date		Name of Patentee or	т6
	ials*	No.1	Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	MM-DD-YY		A	oplicant of Cited Document	
			<u> </u>					<u> </u>
F		Cito				PATENT LITERATU	RE DOCUMENTS n appropriate), title of the item (book, magazine,	
Initia	niner als* .	Cite No.1	journal, serial, sym	posium, catalog, e	tc.), date,	page(s), volume-issue nu published	mber(s), publisher, city and/or country where	T⁰
J	ΓL	C1	CLARK, E.A., et al., G	enomic Analysis o	f Metasta	sis Reveals an Essential R	Role for RhoC, Nature, 2000, pp.532-535,	
			<del></del>	M. et al. Delineat	ion Of Pro	ognostic Biomarkers In Pro	estate Cancer, Nature, August 23, 2001, pp.	
		C2	822-826, volume 412.	•				
		i	FOROZAN, F., et al.,	Comparative Gend	mic Hybri	dization Analysis of 38 Bro	east Cancer Cell Lines: A Basis for Interpreting	
		C3	Complementary DNA	Microarray Data, C	ancer Re	search, 2000, pp. 4519-45	525, volume 60.	
				•	•	, ,	on in the nude mouse model of human prostate	
		C4	1		ual Meetin	g of the American Associa	ation for Cancer Research, April 6-10, San	
<del></del>			Francisco, CA 43:462		m of Boo	ion Desetatio Hypograpia i	Payrollod by aDNA Microarray Analysis	<del> </del>
		C5	Prostate, 2002, pp.189		ne oi ben	ign Frostauc nyperplasia i	Revealed by cDNA Microarray Analysis,	
		<del></del>	<del></del>		and Benio	n Prostatic Hyperplasia: M	folecular Dissection By Gene Expression	
	ľ	C6	Profiling, Cancer Rese		_			

Examiner Signature	/Jerry Lin/	Date Considered	06/14/2006
L	<u> </u>		

Normal Tissue Examined of Oligonucleotide Arrays, Cancer Research, April 1, 2001, pp. 3124-3130, volume 61.

MAGEE, J.A., et al., Expression Profiling Reveals Hepsin Overexpression In Prostate Cancer; Cancer Research, 2001, pp.

NOTTERMAN, Daniel. A., et al., Transcriptional Gene Expression Profiles of Colorectal Adenoma, Adenocarcinoma, and

C7

**C8** 

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

	Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Complete if Known
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application N .	10/660,434
	Filing Date	September 10, 2003	
SIAI	EWENT BY APPLICANT	First Named Inventor	Guennadi V. Glinski
		Art Unit	Not yet known
	man plas 40103	Examiner Name	Not yet known
Sheet	2 of 4 2	Attorney Docket Number	23543-07570

ncr 1 5 2003

Examiner	1 Cits 1	OTHER REFERENCES - NON-PATENT LITERATURE DOCUMENTS	1
nitials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, seed, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	Τ <sup>6</sup>
JL	C9	PEROU, C.M., et al., Distinctive Gene Expression Patterns in Human Mammary Epithelial Cells and Breast Cancers, Proc. Natl. Acad. Sci. USA, 1999, pp. 9212-9217, volume 96.	
	C10	PEROU, C.M., et al., Molecular Portrait of Human Breast Tumors, Nature, 2000, pp. 747-752, volume 406.	
	C11	POŁACK, J.R., et al., Genome-Wide Analysis of DNA-Copy Number Changes Using cDNA Microarrays, Nature Genetics, 1999, pp. 41-46, volume 23.	
	C12	RHODES, D.R., et al., Meta-analysis of Microarrays: Interstudy Validation of Gene Expression Profiles Reveals Pathways  Dysregulation in Prostate Cancer, Cancer Research, 2002, pp. 4427-4433, volume 62.	
	C13	ROSS, Douglas T., et al., Systematic Variation in Gene Expression Patterns in Human Cancer Cell Lines, Nature Genetics, March 2000, pp. 227-235, volume 24.	
	C14	SINGH, D., et al., Gene Expression Correlates of Clinical Prostate Cancer Behavior, Cancer Cell, March 2002, pp. 203-209, volume 1.	
	C15	SØRLIE, Therese, et al., Gene Expression Patterns of Breast Carcinomas Distinguish Tumor Subclasses with Clinical Implications, Proc. Natl. Acad. Sci. USA, September 11, 2001, pp. 10869-10874, volume 98, number 19.	
	C16	STAMEY, T.A., et al., Molecular Genetic Profiling Of Gleason Grade 4/5 Prostate Cancers Compared to Benign Prostatic Hyperplasia, J.Urol., December 2001, pp. 2171-2177, volume 166(6).	
	C17	SU, Andrew I., et al., Molecular Classification of Human Carcinomas by Use of Gene Expression Signatures, Cancer Research, October 15, 2001, pp. 7388-7393, volume 61.	
	C18	VAN'T Veer, Laura J., et al., Gene Expression Profiling Predicts Clinical Outcome of Breast Cancer, Nature, January 31, 2002, pp. 530-536, volume 415.	
	C19	WELSH, J.B., et al., Analysis of Gene Expression Identifies Candidate Markers and Pharmacological Targets in Prostate Cancer, Cancer Research, 2001, pp. 5974-5978, volume 61.	
	C20	WELSH, J.B., et al., Analysis of Gene Expression Profiles in Normal and Neoplastic Ovarian Tissue Samples Identifies Candidate Molecular Markers of Epithelial Ovarian Cancer, Proc. Natl. Acad. Sci. USA, January 30; 2001, pp. 1176-1181, volume 98, number 3.	

Examiner Signature	/Jerry Lin/	Date Considered	06/14/2006	
-----------------------	-------------	--------------------	------------	--

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Senter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

aperwork Reduction Act of 1995, no persons are required to respond to a collection of Information unless it contains a valid OMB control number.

C: TRANS Substitute for form 1449A/PTO

Sheet

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Submitted 12/22/03

		_
	Complete if Known	1
Application N .	10/660,434	
Filing Date	September 10, 2003	
First Named Inventor	Guennadi V. Glinskii	
Art Unit	Not yet known 1651	
Examiner Name	Not yet known	
Attorney Docket Number	23543-07570	

			U.S. PATENT DO	CUMENTS
•		Document No.		
Examiner Initials*	Cite No.1	Number – Kind Code <sup>2</sup> (if known)	Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		US-		

			FOREIGN PAT	FENT DOCUMENTS	-
		Foreign Patent Document		·	
Examiner Initials*	Cite No.1	Country Code <sup>3</sup> – Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T <sup>6</sup>
· · ·					

		OTHER REFERENCES - NON-PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>6</sup>
JL	CX	BHATTACHARJEE, ARINDAM, et al.; Classification Of Human Lung Cardnomas By mRNA Expression Profiling Reveals Distinct Adenocarcinoma Subclasses; Proc. Natl. Acad. Sci.; November 20, 2001; pp. 13790-13795; vol. 98, no. 24.	
	C23	BUCKHAULTS; PHILLIP, et al.; Secreted And Cell Surface Genes Expressed in Benign And Malignant Colorectal Tumors; Cancer Research; October 1, 2001; pp. 6996-7001; vol. 61.	
	C2 23	FUJII, TAKESHI, et al., A Preliminary Transcriptome Map Of Non-Small Cell Lung Cancer, Cancer Research; June 15, 2002; pp. 3340-3346; vol. 62.	
,	CA 24	GIORDANO, THOMAS J., et al.; Short Communication: Organ-Specific Molecular Classification Of Primary Lung, Colon, And Oyarian Adenocarcinomas Using Gene Expression Profiles; American Journal of Pathology; October 2001; pp. 1231-1238; vol. 159, no. 4.	
	C8 25.	GLINSKII, G.V., et al.; Microarray Gene Expression Analysis Of Tumor Progression In The Nude Mouse Model Of Human Prostate Cancer, In Proceedings of the 93 <sup>rd</sup> Annual Meeting for the American Association for Cancer Research; Abstract #4480; April 6-10, 2002; 43: 462.	
	CB	GORDON, GAVIN J., et al.; Translation Of Microarray Data Into Clinically Relevant Cancer Diagnostic Tests Using Gene Expression Ratios in Lung Cancer And Mesothelioma; Cancer Research; September 1, 2002; pp. 4963-4967; vol. 62.	,
	C7 a7	LATULIPPE, EVA, et al.; Comprehensive Gene Expression Analysis Of Prostate Cancer Reveals Distinct Transcriptional Programs Associated With Metastatic Disease; Cancer Research; August 1, 2002; pp. 4499-4506; vol. 62.	
1	C8 28	MONNI, OUTI, et al.; Comprehensive Copy Number And Gene Expression Profiling Of The 17q23 Amplicon In Human	

Examiner Signature	/Jerry Lin/	Date Considered.	06/14/2006
L			l <u>.</u>

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

'Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 6Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

aperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Under U

Sheet

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Submitted 12/22/03

	Complete if Known	
Application No.	10/660,434	
Filing Date	September 10, 2003	
First Named Inventor	Guennadi V. Glinskii	-
Art Unit	Not yet known /65/	
Examiner Name	Not yet known	
Attorney Docket Number	23543-07570	

Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>©</sup>
JL		Breast Cancer, Proc. Natl. Acad. Sci.; May 8, 2001; pp. 5711-5716; vol. 98, no. 10.	
	C8 29	MOUSSES, SPYRO, et al.; Clinical Validation Of Candidate Genes Associated With Prostate Cancer Progression in The CWR22 Model System Using Tissue Microarrays; Cancer Research; March 1, 2002; pp. 1256-1260; vol. 62.	
•	C107 30	1 200 1; DD, 2503-2500; VOI, 284.	
	C1131	RAMASWAMY, SRIDHAR, et al.; DNA Microarrays In Clinical Oncology; Journal of Clinical Oncology; April 1, 2002; pp. 1932-1941; vol. 20, no. 7.	
4	C12 32	SAVERIO, BETTUZZI, et al., Tumor Progression is Accompanied By Significant Changes in The Levels Of Expression Of Polyamine Metabolism Regulatory Genes And Clusterin (Sulfated Glycoprotein 2) in Human Prostate Cancer Specimens; Cancer Research; January 1, 2000; pp. 28-34; vol. 60.	
	C18 33	SHOU, JIANYONG; et al.; Expression Profiling Of A Human Cell Line Model Of Prostatic Cancer Reveals A Direct Involvement Of Interferon Signaling In Prostate Tumor Progression; Proc. Natl. Acad. Sci.; March 5, 2002; pp. 2830-2835; vol. 99, no. 5.	
	C14 34	SU, ANDREW I.; et al.; Large-scale Analysis Of The Human And Mouse Transcriptomes; Proc. Natl. Acad. Sci.; April 2, 2002; pp. 4465-4470; vol. 99, no. 7.	
	C15 35	SUGITA, MICHIO, et al.; Combined Use Of Oligonucleotide And Tissue Microarrays Identifies Cancer/Testis Antigens As Biomarkers In Lung Carcinoma; Cancer Research; July 15, 2002; pp.3971-3979; vol. 62.	

Examiner Signature	/Jerry Lin/	Date Considered	06/14/2006
	<u> </u>		

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&#</sup>x27;Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>6</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

## FROM-Fenwick & West CTR844 RECEIVED 415 281 1350 CENTRAL FAX CENTER

T-577 P.005/009 F-555

PTO/SB/08A (10-01)

APR 1 5 2005
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of Information unless it contains a valid OMB control number.

	Substitute for fo	om 1449/	VPTO	Complete if Known		
INITA	DAZA TION	nie	CI ACIIDE	Application No.	10/660,434	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Filing Date	September 10, 2003	
			PLICANI	First Named Inventor	Guennadi V. Glinskii	
				Art Unit	1651	
84hmitted 415/05				Examiner Name	Unassigned	
Sheet	1 1	of	1	Attorney Docket Number	23543-07570US	

U.S. PATENT DOCUMENTS							
		Document No.					
Examiner Initials*	Cite No.1	Number – Kind Cade <sup>2</sup> (if known)	Date MA-DD-YYYY	Name of Patentee or Applicant of Citad Document			
JL		US-6,455,280 B1	09-24-2002	Edwards, et al.			
1		US-2002/0032319A1	03-14-2002	Cargill, et al			
		US-2002/0119451A1	08-29-2002	Usuka, et al.			
	1	US-2003/0175961A1	09-18-2003	Herron			

	FOREIGN PATENT DOCUMENTS							
		Foreign Patent Document						
Examiner Initials	Cite No."	Country Code <sup>3</sup> — Number <sup>4</sup> Kind Code <sup>3</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	79			

•		OTHER REFERENCES - NON-PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.'	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>6</sup>
	+	PCT international Search Report for POT Application No. PCT/US03/28707, dated	
	1	1.00 0005 4	<u> </u>
	.I	I Walch To, 2005, 4 pages.	$\overline{}$
			1
	+		1
	<u> </u>		<u> </u>
	T		
	<del>                                     </del>		+
	1		L
	+		T
	.1		<del>}</del>
			1
	<del> </del>		1
	1		1

Examiner Signature	/Jerry Lin/	Date Considered	06/14/2006
	1		<u> </u>

<sup>\*</sup>EXAMPLER: tritisal if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&#</sup>x27;Applicant's unique disation designation number (optional). \*See Kinds Codes of USPTO Petent Documents at www.uspto.gov or MPEP 901.04. \*Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3), \*For Japanese patent documents, the Indication of the year of the reign of the Emperor must precede the serial number of the patent document. "Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to piece a check mark here if English language Translation is prached.

PTO/SB/06A (10-01)
Approved for use through 10/31/2002, OMB 0651-0031
Under the Paperwork Reduction Act of 1895, no persons are required to respond to a collection of information unless a contains a valid OMB control number.

Substitute for form 1449A/PTO		Complete if Known
INFORMATION DISCLOSURE	Application No.	10/660,434
STATEMENT BY APPLICANT	Filing Date	September 10, 2003
	First Named Inventor	Guennadi V. Glinskii
make Il 1 / loulo	Art Unit	1651
Sheet 1 1 05	Examiner Name .	Unassigned
Sheet 1 of 1	Attorney Docket Number	23543-07570US

U.S. PATENT DOCUMENTS						
	L	Document No.				
Examiner Initials*	Cite No.1	Number - Kind Code <sup>2</sup> (if known)	Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document		
JL		US-6,506,594	01-2003	Barany, et al.		
JL		US-6,451,525	09-2002	Blasband, et al.		
	<del></del>					

FOREIGN PATENT DOCUMENTS								
		Foreign Patent Document						
Examiner Initials*	Cite No.1	Country Code <sup>3</sup> – Number <sup>4</sup> Kind Code <sup>6</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	10			
	<u> </u>							

Examiner	0.00	OTHER REFERENCES - NON-PATENT LITERATURE DOCUMENTS	
Initials*	Cile No.1	Include name of the author (in CAPITAL LETTERS), the of the article (when appropriate), the of the tem (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	Τ°
			_
	<u> </u>		-
			<u> </u>
			L_
	<del></del> -		
			├
			<u> </u>
			ĺ
			-

Examiner Signature	/Jerry Lin/	Date Considered	06/14/2006

<sup>\*</sup>EXAMINER; Initial If reference considered, whether or not citation is in conformance with MPEP 608. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

<sup>&#</sup>x27;Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-latter code (WIPO Standard ST.s). For Japanese patent documents, the Indication of the year of the reign of the Emperor must precede the sarial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST, 16 if possible. "Applicant is to place a check mark here if English language Translation is shacked.